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Michigan Association of Health Plans

House Health Policy Committee
November 5, 2018

Testimony of Michigan Association of Health Plans in opposition of SB 492

Good afternoon Chairwoman Vaupel and members of the committee, my name is Christine Shearer, Deputy Director of Legislation and Advocacy for the Michigan Association of Health Plans. With me today is Karen Jonas, MAHP Pharmacy Consultant.

As many of you already know, we are opposed to Senate Bill 492. However, we don't want anyone to misinterpret our position as one of insensitivity. Cancer is a devastating illness whose impact has probably personally affected a significant number of individuals in this room.

As health plans, we understand the physical, emotional and financial toll that cancer can have on individuals and their families. That is why our health plans provide coverage for all FDA-approved anticancer medications – both orally administered and intravenously administered.

Michigan is unique, compared to other states, in that chemotherapy coverage has been mandated since 1989. Other states that introduced legislation in discussion today did not have such a mandate in their insurance code, a glaring fact that proponents of these bill have not been forthcoming on. In addition, proponents of the legislation have been misleading in their discussions with the public and to policymakers that this bill will impact all Michigan residents and will lower chemotherapy costs in for all health insurance policies.

Prior to 2006 and the implementation of Medicare Part D, anticancer medication therapy was only covered under the medical benefit as a physician administer service. When Medicare Part D was implemented, Congress unfortunately did not provide statutory authority to move all drug coverage under the prescription benefit, thereby creating a bifurcated system of drug coverage of anticancer medications, and other drugs; with some covered under the medical benefit and others under the pharmacy benefit. This legislation will not correct this issue and therefore will not impact patients covered under government programs, particularly Medicare, which so happens to represent the primary population of individuals afflicted with cancer.

Bills similar to SB 492 have been introduced for the last 5 sessions, or the last 10 years. During that time NOT ONE person has testified in support of this effort would have actually been helped by this legislation. This year MAHP extend ourselfs to assist your offices in your consitituent issues on this issue. To date we have talked with 26 of your consitituents and NOT one of those prople would be helped by this legislation.

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Likewise patients covered under other exempted programs such as Medicaid, Tricare, and ERISA programs will also not be affected by this legislation. Proponents of this legislation have unfairly promoted this legislation as providing coverage relief and cost-savings to Michigan residents, which is not the case, and have only created more confusion on coverage for cancer drug treatment. I have included for you a breakdown of what the impact is for Michigan Citizens.

I will now turn it over to Karen Jonas, to speak further on the drug cost of cancer therapy.

Proponents of the legislation have identified the goal to lower cost-sharing requirement for oral chemotherapy drugs on par with those of intravenously administered chemotherapy. They have identified that goal to lower the cost; however, they have not directed a solution to that goal in this legislation. The root cause of the concern identified is the high cost of cancer treatment. We agree that the costs of cancer drug treatment is excessive and unsustainable for the health care system.

The cost of cancer drug treatment has risen dramatically over the past 15 years and is continuing to rise. The cost of new chemotherapy drugs continues to grow far ahead of inflation. The average cancer drug price per treatment year was less than $10,000 before 2000 and had increased to $50,000 by 2005. In 2012, 12 of the 13 newly approved cancer drugs were priced over $100,000 per year of therapy. The newest cancer drug treatment Kymriah, (a one-time intravenous treatment) approved this year, comes with an ultra-expensive $475,000 price tag. Michigan Medicaid has identified four patients that are being treated with Kymriah at a price tag for the state of 2+ million dollars for 1 drug alone.

The U.S. approved 33% more new cancer drugs than European nations including the United Kingdom, France and Germany within the last decade and approved them must faster according to a study by the Tufts Center for the Study of Drug Development. The study also noted that Americans pay greater for access to cancer drug treatment compared to other countries and in addition that there is no evidence as to whether the increased access to new cancer drugs and the higher cost translates to better results for cancer patients.

Unlike the European drug approval process, the FDA does not approve drugs on evidence of benefit on survival or quality of life outcomes. Because of this difference several cancer drugs approved for use in the U.S. were not approved for use in Europe (Dendreon's Provenge, for prostate cancer and Pfizer's Xalkori, for non-small cell lung cancer).

I have included with this testimony some examples of anticancer medications whose high cost do not translate to improved health outcomes as well as cost variance of anticancer medications in the US compared to other countries.

Price controls on health plans for anticancer drugs, does not adequately address the fundamental problem of cancer treatment, which is the soaring cost of prescription drugs.

Ironically, some of the most vocal companies supporting price controls on insurers are the pharmaceutical drug manufacturers themselves set the price of the drugs. Pharmaceutical manufacturers around the country and in states, like Michigan, are backing legislation that would force caps on co-payments for drugs or mandates on coverage instead of themselves providing options to ensure patient access to drugs by making medications affordable. $40,000 drugs and $475,000 drug therapy is not affordable.

Pharmaceutical drug manufacturers have one of the highest profit margin in the industrial sector. Capping co-pays, as this legislation would do, without addressing the underlying price of the drug and their profit margins, shifts the high cost of drugs to employer groups and rises the cost of coverage and premiums.

Unfortunately, solutions addressing cost of cancer therapy for the majority of your constituents need to be directed at a federal level.

I will now turn it back over to Christine for summary possible options that will actually assist your constituents.

Let Summarize:

FACTS:

- There is a very valid concern here.
- MI is the only state that already has a mandate on the books.
- This bill will not help the majority of Michigan citizens.
- MI Cancer Society has an amazing grassroots, though miss informed.
- Let redirect these folks to lobby Michigan congressional delegation, Medicare! No one can afford $3500/month out-of-pocket.
- This bill does not address the high cost of drug prices.
- Oncology drugs are the most expensive category of medications.
- Voting YES on this bill will be giving PHARMA a black check.

Recommend solutions:

- Tie bar this bill to full Drug Price Transparency legislation.
- Introduce legislation that requires Pharmaceutical sales reps to have to disclose the cost of their drug when meeting with physicians.
- Draft example letter for your constituents to lobby their congressional lawmakers, who can help them.
- Introduce legislation that would establish a Mandate Review Commission
- At the federal level - clarify the definition of a drug under Medicare regardless of the rout of administration, the ability to negotiate drug prices in the U.S. like in other countries and additional pricing models such as requiring the use of the 340B Drug Pricing Program or mandatory Pharmaceutical Patient Assistance for anticancer drugs. This would truly allow patients, physicians, payers and healthcare purchasers to achieve lower costs for cancer drug therapy.

In Conclusion:

In typical form, rather than addressing the underlying price of medications and treatments, drug makers are looking to hide their record-breaking costs increases behind insurance providers or in this case MI Cancer Society. Capping co-pays, as this legislation would do, without addressing the underlying price of the drug and their profit margins will only drive up the cost of coverage and premiums. With most new treatment carrying a six-figure price tag, shouldn't drug companies be upfront and transparent about why we're paying so much than other countries for their products?

Michigan can no longer afford to walk around the problem of drug pricing. Shifting blame may have worked in the past, but when public health and access to vital medicines continue to be threatened by these excessive increasing prices, we all need to step up and work toward a better way to solve this problem for patients.

We are more than happy to answer any questions you may have.

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Strategies to address the unsustainable costs of cancer drugs in the US

Written by Craig E. Devoe, MD, Acting Chief, Division of Hematology and Medical Oncology, Northwell Health | June 23, 2017 | Print | Email

Patients with cancer are often extremely ill, emotionally distressed and vulnerable. Medical oncologists routinely prescribe medications that are extraordinarily expensive, and patently unaffordable at full market price.

Oral chemotherapies are particularly problematic in that they are covered under Medicare Part D and listed in the highest tiers of drug formularies. As such, the patient is responsible large co-insurance payments (20% to 30% of the total costs) due to cost-shifting policies that have occurred over the past decade.[1] The pharmaceutical industry and third-party payers engage in finger-pointing, whereby the manufacturers claim outrage that patients are forced to participate in the costs of the drugs, and payers claim that the prices are too high to fully cover. These financial hurdles have been shown to undermine drug access and patient adherence and have created a new literature on "financial toxicity"[2]. Out of pocket expenses for one drug could be over $20,000 to $30,000 per year, which is nearly half of the average annual household income in the US ($52,000 in 2013).[3] One of the enabling mechanisms for the continual rise in prices is consumer silence. Through the efforts of their treating physicians and specialty pharmacies, many patients obtain financial assistance from charitable organizations to partially offset their copays. In turn, these wealthy charities are funded to levels of over $1 billion by the same pharmaceutical manufacturers that are driving up prices. Under the "cover" of charitable contributions, pharmaceutical companies can bypass the Anti-Kickback Statute, increase prices and revenue, and even earn tax credits.[4] While the Center for Medicare & Medicaid Services (CMS) and private insurers continue to finance the growing burden, consumers have not organized and provided sufficient vocal opposition due to the morbidity of their illness, dependency on the system, or frank unawareness.

Nationally, the cost of cancer drugs in the US was over $100 billion in 2015, and estimated to increase to $147 billion in 2018.[5] Three key drivers of overall cancer care cost increases have been described: the percent increase in per-patient cost which is similar to the cost of care in the non-cancer population; site of service for chemotherapy shifting from physician offices to higher-cost hospital outpatient settings; and per-patient cost of chemotherapy drugs.[6] This last driver is increasing at a much higher rate than the others. The public debate on cancer drug costs is a subset of the larger cost debate regarding all prescription drugs. This debate has generally centered-around the pros and cons of price regulation, which is thought to lower consumer costs in the short term, but possibly inhibit innovation due to decreased pharmaceutical revenues.[7] Not to be overlooked or understated is the fact that 5 year cancer survival rates have improved by 20% over the past 20 years.[8] Investment and innovation in cancer prevention and treatment have both contributed to this improvement; however the rising annual costs are not sustainable.

Determinants of drug prices

Oncology drug costs far exceed the average costs of non-cancer drugs. In the 1970's the average cost of a month of therapy was $170, and by 2014 it was $10,000.[9] Since 2012, 12 of 13 newly FDA-approved cancer drugs were priced above $100,000 annually.[10] Additionally, some of these drugs must be given in combination to achieve maximal clinical response, such as immune-therapeutics. The FDA-approved combination of a PD-1 inhibitor (nivolumab) and a CTLA-4 inhibitor (ipilimumab) for metastatic melanoma given for one year is priced at approximately $250,000, which is more than the cost of an average US house.[11] Immunotherapy utilization will dramatically increase over time, since the indications forimmunotherapy have expanded to more prevalent diseases such as lung cancer, and it is being actively

studied in all other cancers. If research and development costs were the sole basis for drug pricing, then unit production costs should drop as the number of indications expand, and prices should drop as well, but this does not happen.[12] Granted, the costs of R&D and company risk-taking are real and need to be considered and reconciled. The cost for the development of each new FDA-approved drug has been controversially calculated at $2.6 billion.[13] Among other assumptions, this figure includes the costs of failure, wherein 90% of all drugs entering clinical trials do not achieve approval. However, pharmaceutical companies are often not the site of discovery of disruptive innovation, rather it is in the academic world where National Institutes of Health (NIH) funding generally supports such breakthroughs. It is estimated that 85% of cancer-related basic research is paid for through taxpayer dollars, whereas pharmaceutical companies spend only 1.3% of their revenues on basic research.[14] Unfortunately, since 2003 there has been a 25% decrease in inflation-adjusted funding of the National Cancer Institute (NCI) budget, which was $5.2 billion in 2016.[15] In the non-cancer realm, the blockbuster anti-HCV drug sofosbuvir (Harvoni) was initially priced at $94,000 for a 12 week course, whereas the production costs were in the range of $68 to $136.[16] In comparison, this same 12 week course is sold in India for $300. To acquire the drug rights, Gilead had purchased the start-up biotechnology company that was created on the basis of the work of an NIH-funded professor at Emory. Gilead earned $12 billion in 2014, and the US government paid a large portion of that bill through CMS. Indeed there is a significant element of social injustice where Americans with cancer pay 50% to 100% more for the same brand-named drug than patients in other countries, and it is also their tax dollars that subsidize most of the basic research. The CMO for Express Scripts, the largest pharmacy benefit management organization in the US, supports the concept that some of the financial burden should be shifted to other countries.[17]

Drug prices may be influenced by a variety of factors besides R&D costs: competition within the pharmaceutical industry; corporate policies and obligations to investors; and governmental policies regarding competition and patent law. The latter policies are particularly problematic in that they have created anomalies in market forces which prevent them from naturally adjusting prices lower; instead prices are moving upward, limited only by what the market will bear. The two main anomalies in market forces that permit high prices are "protection from competition" and lack of "payer negotiating power."[18] Federal law grants both market- and patent-related exclusivity for brand drugs. These factors provide companies with monopoly rights for a defined period of time before a generic can be sold (5-7 years for small molecules and 12 years for biologics), and protects them from competition.[19] It has been shown that the higher the number of manufacturers competing to produce equivalent generics, the lower the price will decline. For example, if more than five companies compete, the generic price can fall below 20% of brand price.[20] As such, non-profit lobby organizations such as the National Coalition on Health Care have strongly supported policies that would facilitate approval of cheaper generic options, along with transparency in launch price and comparative effectiveness research to drive down prices.[21] To extend the duration of their protected pricing, pharmaceutical companies may further prolong market exclusivity through "pay for delay" tactics; whereby generic manufactures are paid to delay production of their generic versions of the brand drug. In such cases, both the brand manufacturer and the would-be generic manufacturer share in the profits of an exclusive market position. The consumer (the patient) remains a victim of continued price escalation. It is this "government-protected monopoly rights for drug manufacturers" that appears to be the most important factor in in driving prices higher in the US.[22]

The second market anomaly is the lack of payer negotiating power. Specifically, some Federal agencies are prohibited by law from negotiating prices of drugs, as a result of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003.[23] Despite the fact that Medicare accounts for 29% of drug expenditures in the US, CMS cannot leverage its purchasing power to negotiate for lower prices. Moreover, CMS is obligated to provide broad coverage, including all drugs in the oncology space. However, a precedent has been set, whereby another federal agency has a different set of rules. The Veterans Health Administration (VHA) is eligible for a rebate of at least 24% of the average selling price, and has the authority to exclude products from its formulary.[24] California attempted to pass Proposition 19

in November 2016, whereby it would require State government programs to pay no more than the VHA. This was voted down after pharmaceutical groups spent tens of millions of dollars to defeat this ballot, arguing that it would limit patient access to innovative drugs.[25]

Additional inefficiencies in the private and public sectors also create an environment for high prices. From the governmental perspective, the Office of Generic Drugs at the FDA has had a slow application process for generic drugs, which may delay generic rollouts by years. From an industry perspective, there is an enormous redundancy in the clinical trials that study variations of the same basic drug, and fail to share data with each other. This has been seen for many years with next-in-class ("me-too") drugs that target high profit market positions, such as cholesterol lowering agents, gastric proton pump inhibitors, and anti-hypertensives. A current example of this in the cancer market is immunotherapeutic checkpoint inhibitors. There are ~800 clinical trials that are testing various combinations of immunotherapy using a dozen different antibodies designed by a dozen different companies to inhibit the same target (PD-L1).[26] Moreover, the dollars and research infrastructure that are utilized to generate me-too drugs create an opportunity cost whereby they are not being invested in new and yet unproved ideas.[27] Clearly, the goal of pharmaceutical research is not only to strive to cure human cancer; rather to also partake in the profits of a highly lucrative market.

Solutions

The problems are clear, but solutions have been difficult to implement due to the large number of stakeholders, and the complexity and political nature of the issues surrounding drug pricing. The pharmaceutical lobby is powerful, the government is divided, third party payers have not been able or willing to negotiate, health system consolidation is driving overall costs higher, and patients continue to suffer the burden of collective inaction. Since deliberate governmental intervention such as the MMA had created the conditions for high prices, it is mandatory that it play a role in solving this issue. Public policy is starting to move towards decreasing the competitive protection afforded to brand drug producers. A recent Supreme Court decision voted 5 to 3 in favor of overturning an 11th Circuit court decision that a "reverse payment settlement"(type of "pay for delay") does not violate anti-trust laws.[28] The dissenting Supreme Court judges believe that the status quo position is acceptable, stating that the point of patents is to "grant limited monopolies as a way of encouraging innovation."[29] However, as the Harvoni example demonstrates, innovation primarily resides in academia. As such, this speaks loudly towards the benefits of a significant increase in the NIH &NCI budget, rather than dollars spent supporting massive drug manufacturer profits. Workman et al describe the need for new academic models of drug discovery and the infrastructure to support these programs.[30] Academic drug discovery provides more freedom and incentive to engage in the types of challenges that would be seen as too risky by the pharmaceutical and biotechnology industry.[31]

Another potential solution is to expand the market and increase competition by importing drugs from outside of the US. In a bipartisan fashion, Senators have requested that HHS Secretary Tom Price allow importation of drugs from Canada.[32] This came on the heels of yet another new drug being rolled out for muscular dystrophy at $89,000 per year in the US, versus $2,000 per year in Canada. PhRMA (Pharmaceutical Research and Manufacturers of America) representatives have been quick to state that such a policy would risk bringing counterfeit drugs across the border and bypass FDA regulatory standards. Of note, President Trump did support drug importation during his campaign, although it remains to be seen where he will finally land on this issue.[33] PhRMA's solutions for affordability and price sustainability include concepts based around the modernization of drug discovery, development and approval process.[34] The first point concerns the improved efficiency of drug discovery at the scientific and organizational levels, which has been echoed by the scientific community.[35] Moving away from the traditional randomized studies, and using new statistical methods and biomarkers to predict response will help to decrease financial costs, and unnecessary toxicities to the trial subjects.

The 340B pricing program developed by Congress in 1992 was intended to help offset expenses for vulnerable and uninsured patients at safety-net hospitals. Manufacturers are required to deeply discount medications for these facilities; and currently 6% of brand drugs are sold through this program creating a decline in revenue to the pharmaceutical industry of$18 billion. High reimbursements are especially concentrated in cancer medications where 340B pricing may represent up to 60% of hospital-based cancer center revenue.[36] Essentially, enrolled cancer centers can purchase drugs for 30%-40% below average wholesale price (AWP) and are reimbursed from insurers at standard rates AWP+6% or higher. There is a valid concern on behalf of PhRMA that hospital systems have expanded the scope of 340B pricing programs beyond that of the original intent. For example, hospital systems have generally been able to also offer such discount pricing to community practices that they have acquired. Although there is a requirement for a certificate of need and an affiliation with a Disproportionate Share Hospital (DiSH), such expansions have spawned debate regarding the appropriateness of the broad-based application of this program to non-indigent populations. 340B pricing has clearly helped hospital-based cancer programs thrive and create substantial revenue for their parent health system. Moreover, many private practices have joined health systems to gain access to this special pricing as a survival tactic in an environment of declining reimbursement and increased regulation. Because 340B pricing creates revenue to help support a variety of ancillary services with in cancer cancers, the lack of such pricing would cause many centers to operate at a loss and force some to close. The reduction or dismantling of this program is not a solution by itself, and would only be possible as a component of a more comprehensive strategy.

The issue of CMS not having negotiating power regarding drug prices has been a topic of debate for many years. This barrier seems to be a unique situation that is found only in the US. In the UK, the National Institute for Health and Care Excellence (NICE) has been able to limit the approval of drugs based on value measurements below $60,000 quality adjusted life years (QALY). When value-based concepts like this have been raised in the US in the past, the public discourse has immediately turned towards "death panels."[37] Regardless, there is a movement towards value-based pricing that is gaining traction in a variety of clinical professional societies, since physicians are direct witnesses to the financial toxicities borne by their patients, and also must struggle through the bureaucracy to assist their patients.[38] Moreover, since high drug prices often make them unaffordable and inaccessible to cancer patients, it has been suggested by some oncologists that the profession has a "moral obligation to advocate for affordable drugs."[39] ASCO (American Society of Clinical Oncology)[40] and ESMO (European Society of Medical Oncology)[41] are two of a group of professional societies that have developed value-based frameworks for evaluating new cancer drugs. In this context, value is defined as a measure of treatment benefits relative to cost.[42] These frameworks consist of four parts relevant to the discussion of value and price: health outcomes; quality of clinical trial evidence; health benefit determination based on a formula or expert consensus; and value assessment as it relates benefits to cost. The frameworks move away from the world of FDA approval based solely on statistically significant p-values; rather outcomes such as overall survival and more meaningful endpoints are considered. For example, erlotinib (Tarceva) was approved for pancreas cancer in 2005 based on a statistically significant improvement in survival of only 12 days, and at a price of over $4,000 per month.[43] Using these new frameworks, drugs such as this would not be approved at this price, if at all. In fact, value analysis using both the ASCO and ESMO models was applied to 37 FDA cancer drug approvals between 2000 and 2015.[44] Not surprisingly, the authors found that many new FDA-approved cancer drugs do not have high clinical benefit, and that there is no relation between the price of drugs and benefit to patients and society.

Although promising as decision-making tools, the current iteration of value based models are limited by their patient-centric focus. Cost-effectiveness analysis focuses on the individual patient, and does not address the issue of overall budget impact in a system-wide fashion. For instance, the prevalence of chronic HCV is estimated to be 3 to 4 million cases.[45] Although sofosbuvir (Harvoni) may be considered cost effective on an individual level by a QALY measure, due to the sheer number of cases, it is essentially unaffordable at its current price (3.5 million cases x $94,000/case = $332 billion) at a national level.[46] Regardless of the fact that these frameworks require further modeling and refinement, the issue of

implementation is challenging, since various stakeholders perceive value and risk tolerance from different perspectives. There is no one-size-fits-all solution, and future iterations must be adaptable.

Conclusion

Over the past 15 years, much has been written and discussed regarding the increasing costs of drugs, and the concerns and issues that existed then remain intact.[47] The unsustainable pricing epidemic has sustained. The solution to address the costs of cancer drugs in the US is a multi-pronged strategy, with all relevant stakeholders at the negotiation table. Along with the aforementioned, additional impactful ideas are tabulated (Appendix A). As in any interest-based negotiation, all participants must actively listen to the perspectives and priorities of the other parties, find common ground and create new solutions that do not currently exist.[48] Cancer is narrowly in second place to heart disease as the most common cause of death in the US, and a much more common cause of death in young individuals.[49] As such, many of us are or will become a patient with cancer, or become a family member or friend of a cancer patient. It is with this perspective and the realization of our interdependencies that we must enter into negotiation. Innovative pharmaceutical companies should be permitted and encouraged to acquire a reasonable profit from the sale of drugs that create value to the patient and to society. The US government must create an environment where market forces are restored to determine that that balance, and always remain vigilant for unintended consequences from its actions. To catalyze the change process, consumers must organize and advocate for themselves, apply political pressure, and demand just and equitable pricing.[50]

1 (Kaiser, 2015)
2 (O'Conner, et al., 2016)
3 (Kantarjian & Rajkumar, 2015), p 501
4 (Elgin & Langreth, 2016); see (Furrow, et al., 2013) for Anti-Kickback Statute (AKS)42 USC §1320a–7b
5 (Burkholder, 2015), p 842
6 (Fitch, et al., 2016), p 3
7 (RAND, 2008)
8 (Fitch, et al., 2016), p 5
9 (Saltz, 2016)
10 (Workman, et al., 2017), p 579
11 (Workman, et al., 2017)
12 Ibid, p 579
13 (Avorn, 2015)
14 (Kantarjian & Rajkumar, 2015), p 502
15 (NCI, 2017)
16 (Sachs, 2015)
17 (Wieczner, 2016)
18 (Kesselheim, et al., 2016), p 860
19 Ibid, p 861
20 (FDA, 2015)
21 (National Coalition on Healthcare, 2016)
22 (Lupkin, 2016)
23 (Workman, et al., 2017), p 579
24 (Kesselheim, et al., 2016), p 862
25 (Meyer, 2016), p 15
26 (Workman, et al., 2017), p 580
27 (Bach, 2014)
28 (Federal Trade Commission v. Actavis, Inc., 2013), p 5
29 Ibid, p 26
30 (Workman, et al., 2017)
31 Ibid
32 (Dickson, 2017)
33 (Meyer, 2016), p 13

34 (PhRMA, 2017)
35 (Workman, et al., 2017)
36 (PhRMA, 2017), p 9
37 (Meyer, 2016), p 14
38 (Hunter, et al., 2016)
39 (Kantarjian & Rajkumar, 2015), p 501
40 (Schnipper, et al., 2015)
41 (Cherny, et al., 2015)
42 (Chandra, et al., 2016), p 2069
43 (CBSNews, 2010)
44 (Vivot, et al., 2017)
45 (CDC, 2017)
46 (Neumann & Cohen, 2015)
47 (Carey & Barrett, 2001); price of imatinib (Gleevec) was $26,000/year in 2001 and $140,000/year in 2016
48 (Marcus, et al., 2011)
49 (Pathak, 2016)
50 (O'Donell & Shesgreen, 2017)

Stakeholder	Problem	Solution
Provider (Oncologist)	Unaware of drugchoice costs.	"Nudge" towards lower priced, equally efficacious choices.[51]
	Higher income tied to prescribing higher cost drugs (Principal-Agency problem) encourages brand utilization.[52]	Create equivalent reimbursement for high and low cost drugs.[53]
Health System Cancer Center	Dependent on 340B pricing for both indigent and non-indigent cancer patients.	Continue 340B program or create alternate funding sources for cancer center operations.
Government	Patents create limited monopolies.	Streamline generic competition within the US and abroad.
	NIH has historically rejected petitions for "march in" rights as outlined in the Bayh-Dole Act of 1980.[54]	Employ "march in" rights to control excessive pricing for drug discoveries based on NIH funding.[55]
	25% decrease in funding of NCI innovation in academia.	Increase NCI funding.
	Regulated market dynamics affects pricing.	Allow CMS to negotiate price, similar to the VHA. HR-242 and S-41 are two bills introduced in January 2017 that support CMS negotiation rights.[56]
Pharmaceutical	Conflicting priorities of profit and mission.	FDA approval of drugs that create value.
	Tactics to extend monopolies and oligopolies.	Abolish "pay for delay" tactics; enforce anti-trust laws
	Excess reliance on US reimbursement.	Rebalance costs internationally.
Organizations	Disparate value-based frameworks (ASCO, ESMO, ICER).	Unify frameworks; cross-organizational teaming.
Consumer (Patients)	Too ill to fight; victimized; unaware.	Increase awareness, organize, lobby, and leverage family members and survivors.
International Community	Purchases and sells US brand drugs at a fraction of US based prices.	Increase international pricing, with the tradeoff of increased importation of generic drug imports into the US market.

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HEALTH NEWS
APRIL 12, 2018 / 11:24 AM / 8 MONTHS AGO

As cancer drug prices climb, value not keeping pace

Anne Harding

(Reuters Health) - The cost of new anti-cancer drugs increased more than five-fold from 2006 to 2015, but a new analysis suggests that cancer patients and insurers may be getting less for their money.

Anticancer medications account for the lion's share of global drug spending, and the average price per month of these drugs is known to have more than doubled in recent years, Dr. Kelvin Chan of Sunnybrook Health Sciences Centre in Toronto and colleagues note in the Journal of Oncology Practice.

"To justify the increasing prices of novel oncology drugs, a parallel increasing trend in clinical benefit would be expected to ensure that value of these new treatments is maintained over time," the study team writes.

They analyzed 42 clinical trials of anti-cancer drugs approved by the U.S. Food and Drug Administration in 2006-2015 to determine whether the drugs' clinical benefits were also rising as prices climbed. All of the studies were in patients with advanced cancer. Monthly costs for the drugs ranged from $5,454 to $45,004, and the average was $13,176.

The average monthly cost of oncology drugs increased from $7,103 in 2006 to $15,535 in 2015, they found. And the incremental cost of new drugs - meaning the difference in cost between a full course of treatment with the new medication and a course of treatment with the older medication it was intended to replace - increased from $30,447 in 2006 to $161,141 in 2015.

Over the study period, monthly drug costs increased by 9 percent per year, while incremental costs rose by 21 percent per year.

Chan's team used two scales, the American Society of Clinical Oncology (ASCO)'s Value Framework and the European Society of Medical Oncology's (ESMO) Magnitude of Clinical Benefit Scale, to measure clinical benefits of the newly approved drugs. Neither scale showed any improvement in clinical benefit over time, nor were there any associations between the clinical value of a drug and its monthly or incremental cost.

"The cost is going up very steeply, and the improvements tend to be much more incremental, that's really the fundamental issue," Dr. Richard Schilsky, senior vice president and chief medical officer at ASCO, said in a telephone interview.

Cost increases are similar regardless of whether a drug is a "true game changer that revolutionizes the approach to treating a kind of cancer, or the drug just produces a small incremental improvement over an otherwise available therapy," he added.

"Cost is not connected with benefit, and cost is going up quickly, and benefit is highly variable," Schilsky said. "I think that as a society and as a healthcare system we need to introduce and experiment with some strategies that try to restore more normal market forces."

ASCO and other groups are supporting efforts to make cancer drug costs relate to their effectiveness, he added. "We clearly need to do something," he said. "We can't just allow the continued escalation in pricing and cost without making any effort to tie it to the benefits the treatment delivers."

Dr. Chan was not available for an interview by press time.

Pricing for new cancer drugs needs to be examined carefully, Dr. Len Lichtenfeld, deputy chief medical officer for the American Cancer Society, said in a telephone interview. "There are going to be solutions I expect down the line that address the high cost of these drugs," he said.

"That's a legitimate, fair discussion that we need to have," Lichtenfeld added. "Having said that, I also think we need to be looking more carefully at the impact of these drugs on survivorship, quality of life and side effects to get a much better handle on how these drugs impact patients' lives."

Geneticist in baby gene-editing case says he's proud

Pricing of new cancer drugs is "very much what we call a black box," he said, noting that prices of older drugs also often increase, and that sometimes these increases seem to be more than can be justified by increases in marketing and production costs and inflation.

SOURCE: bit.ly/2JzBRw9 Journal of Oncology Practice, March 30, 2018.

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www.medscape.com

'Parity' Laws for Costly Oral Cancer Drugs Not a Solution

End Result Is a Shell Game

Nick Mulcahy | |October 02, 2014

CORRECTED // The much-lauded legislation to protect patients in the United States from the ruinously high cost of oral cancer drugs should not be whole-heartedly cheered, suggest a trio of experts in a Viewpoint essay published online September 22 in *JAMA Internal Medicine*.

The so-called "oral chemotherapy parity laws" — passed in 34 states plus the District of Columbia — require health insurers to cover oral chemotherapeutic agents under "no less favorable" terms than intravenous (IV) chemotherapy. The latter tends to be comprised of old drugs and is much less expensive.

In short, the laws, which have been praised by law makers, physicians, and patient advocates, make oral cancer drugs "more affordable and accessible to patients," write Bo Wang, PharmD, and Aaron Kesselheim, MD, JD, MPH, both from Harvard Medical School in Boston, and Steven Joffee, MD, from the University of Pennsylvania in Philadelphia.

So why do these distinguished analysts also say that the laws are "an inadequate response"?

They explain that the laws "merely shift the responsibility" for the cost of the drugs to insurers, who in turn will inevitably pass the additional costs on to all policy holders.

In other words, some cancer patients might be spared the potential financial ruin resulting from the exorbitant cost of oral agents, such as imatinib (*Gleevec*, Novartis), but all Americans who have health insurance will ultimately pay more for coverage to compensate.

It's a shell game, they suggest.

One thing stays the same under the new laws — the high cost of cancer drugs is not challenged or changed for the United States as a whole, the essayists report. And the cost of cancer medications will continue to go up, they predict.

Indeed, one prominent American oncologist recently pointed out that the prices appear to be set at whatever the market will bear, and noted that recently launched oral cancer drugs are costing more than $100,000 per year.

It is unclear how many patients will actually benefit.

In their Viewpoint, the essayists assert that the parity laws are weakened by the fact that they "only apply to the limited number of private insurance plans," which have "large" discrepancies in cost-sharing arrangements for oral and IV chemotherapy.

"It is unclear how many patients will actually benefit," they state, adding that the continuing legislative focus on these "well meaning" laws "misses the mark."

How Insurance Works in the United States

Dr Wang and colleagues explain how "oral chemotherapy parity laws" work and how the insurance industry is designed to fend off any negative influence on profits.

First, they describe the differences between oral and IV chemotherapy in terms of insurance coverage. The hit to a

patient's pocketbook is likely to be radically different with oral drugs, they report.

Oral cancer drugs are handled through a patient's "pharmacy benefit," whereas IV chemotherapy is handled through what is known as "medical benefit."

Medical benefits (for IV chemo) usually require patients to pay a flat copayment ($20 to $50 per visit) for care in an outpatient setting, which can include the administration of IV medications. In short, the cost to the patient is very modest.

Pharmacy benefits (for oral chemo) are a very different arrangement. They often have a "tiered" copayment structure and other provisions that increase cost-sharing for more expensive medications.

Pharmacy benefits can include coinsurance (patients are responsible for a percentage of the medication cost), high overall deductibles, and caps on annual drug benefits.

The essay spells out what this means for a pair of oral drugs approved by the US Food and Drug Administration in 2012 for the treatment of chronic myelogenous leukemia — ponatinib (*Iclusig*, Ariad), priced at $138,000 per year, and bosutinib (*Bosulif*, Pfizer), priced at $118,000 per year.

If a health insurance plan imposed a typical 25% coinsurance, a patient would then incur monthly out-of-pocket costs of about $2500 for either drug.

By comparison, the copayment for each office visit during which a patient receives IV chemotherapy might be $50, they explain.

Parity laws change all of this — a patient with chronic myelogenous leukemia being treated with a pricey oral drug would end up paying the same $50 charge as a patient being treated with IV chemo.

However, one of the players in the business of drug provision in the United States is not waiting for legislators to change laws.

Pharmacy benefit managers are taking matters into their own hands and refusing to pay for certain drugs.

Recently, Express Scripts and CVS Caremark, the 2 largest such managers in the United States, began excluding certain drugs from their formularies after drug companies refused to provide substantial price reductions.

"The exclusion of certain drugs is a departure from the usual practice of insurers of simply shifting expensive therapeutics to a higher cost-sharing formulary tier," the essayists observe.

"This cost-containment strategy might be considered in oncology, including for newer injectable agents that are priced at levels comparable to that of oral agents," they add.

They cite an example of how the oncology community made a difference. In 2012, the newly launched ziv-aflibercept (*Zaltrap*, Regeneron/sanofi-aventis) for colorectal cancer was initially priced at more than $11,000 a month. This was challenged publicly in the by clinicians at the Memorial Sloan Kettering Cancer Center in New York City, which resulted in a price cut.

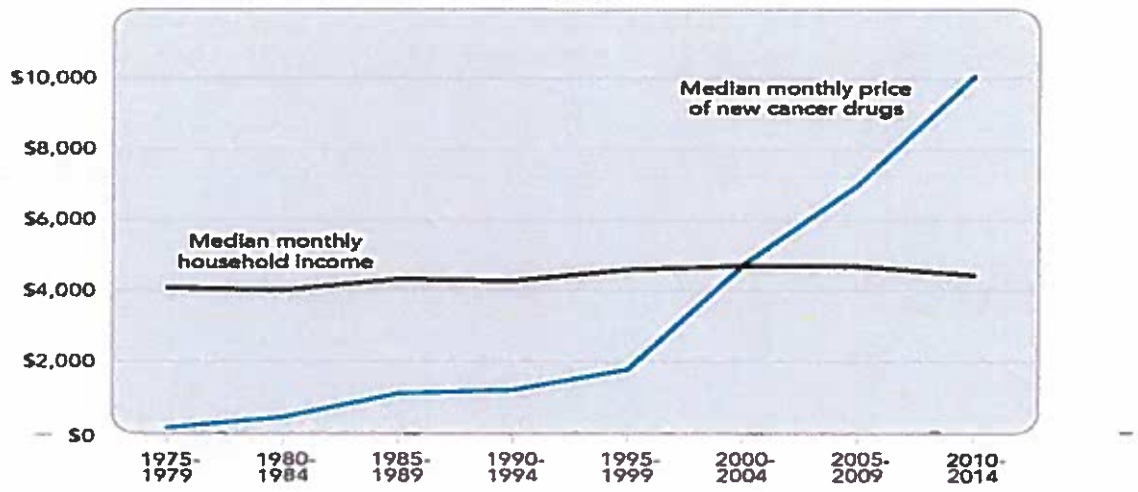
JAMA Intern Med. Published online September 22, 2014. Abstract

***Editor's note** : The incorrect reference to pertuzumab as an oral agent has been removed.*

Send comments and news tips to news@medscape.net.

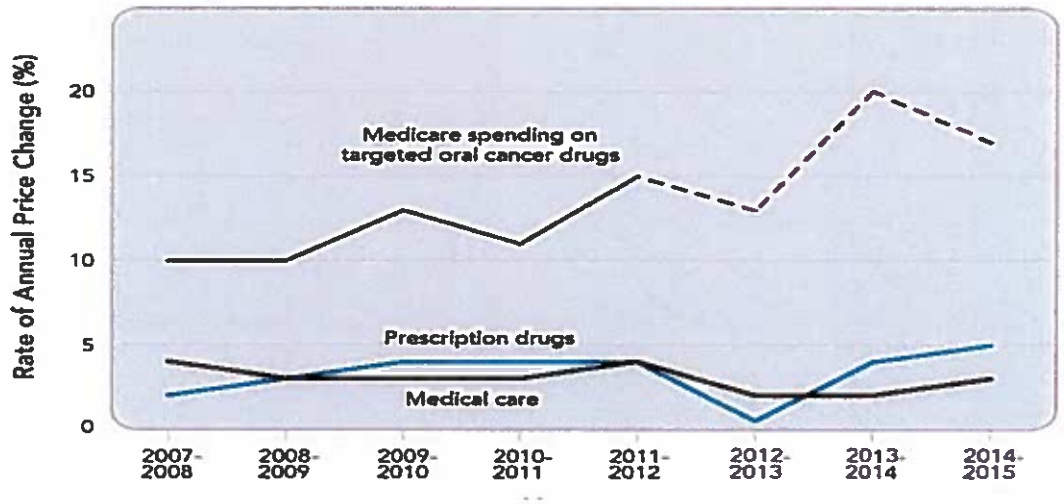
Cite this article: 'Parity' Laws for Costly Oral Cancer Drugs Not a Solution. *Medscape.* Oct 02, 2014.

Launch Price of New Cancer Drugs Compared with Household Income, 1975-2014



Source: President's Cancer Panel https://prescancerpanel.cancer.gov/report/drugvalue/ExecutiveSummary.html 2018

Price Changes for Targeted Oral Cancer Drugs, Medical Care, and Prescription Drugs, 2007-2015



Source: President's Cancer Panel https://prescancerpanel.cancer.gov/report/drugvalue/ExecutiveSummary.html 2018

Oral Chemotherapy Parity Legislation (SB 492)

NOV - 2018

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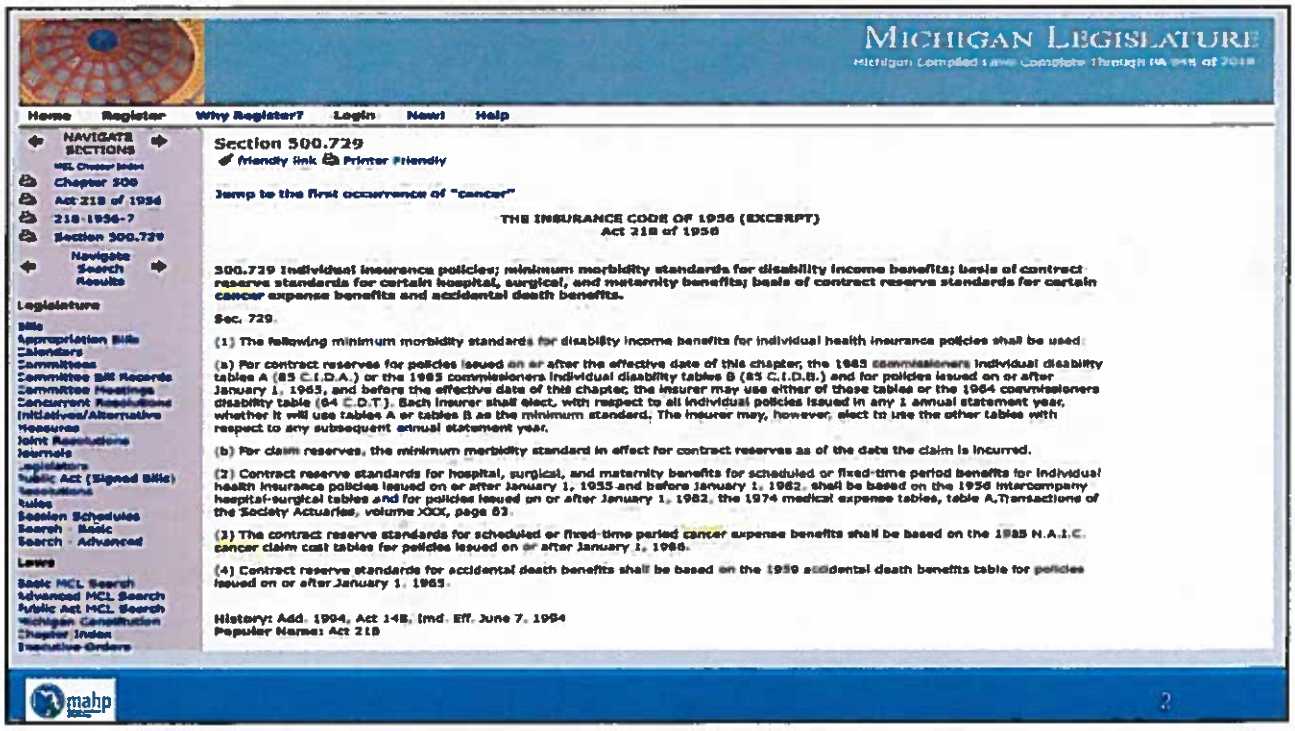

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NAVIGATE SECTIONS

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Jump to the first occurrence of "cancer"

THE INSURANCE CODE OF 1956 (EXCERPT)
Act 218 of 1956

500.729 Individual insurance policies; minimum morbidity standards for disability income benefits; basis of contract reserve standards for certain hospital, surgical, and maternity benefits; basis of contract reserve standards for certain cancer expense benefits and accidental death benefits.

Sec. 729.

(1) The following minimum morbidity standards for disability income benefits for individual health insurance policies shall be used:

(a) For contract reserves for policies issued on or after the effective date of this chapter, the 1965 commissioners individual disability tables A (65 C.I.D.A.) or the 1965 commissioners individual disability tables B (65 C.I.D.B.) and for policies issued on or after January 1, 1965, and before the effective date of this chapter, the insurer may use either of those tables or the 1964 commissioners disability table (64 C.D.T). Each insurer shall elect, with respect to all individual policies issued in any 1 annual statement year, whether it will use tables A or tables B as the minimum standard. The insurer may, however, elect to use the other tables with respect to any subsequent annual statement year.

(b) For claim reserves, the minimum morbidity standard in effect for contract reserves as of the date the claim is incurred.

(2) Contract reserve standards for hospital, surgical, and maternity benefits for scheduled or fixed-time period benefits for individual health insurance policies issued on or after January 1, 1955 and before January 1, 1982, shall be based on the 1958 intercompany hospital-surgical tables and for policies issued on or after January 1, 1982, the 1974 medical expense tables, table A, Transactions of the Society Actuaries, volume XXX, page 83.

(3) The contract reserve standards for scheduled or fixed-time period cancer expense benefits shall be based on the 1985 N.A.I.C. cancer claim cost tables for policies issued on or after January 1, 1986.

(4) Contract reserve standards for accidental death benefits shall be based on the 1959 accidental death benefits table for policies issued on or after January 1, 1965.

History: Add. 1964, Act 148, Imd. Eff. June 7, 1964
Popular Name: Act 218

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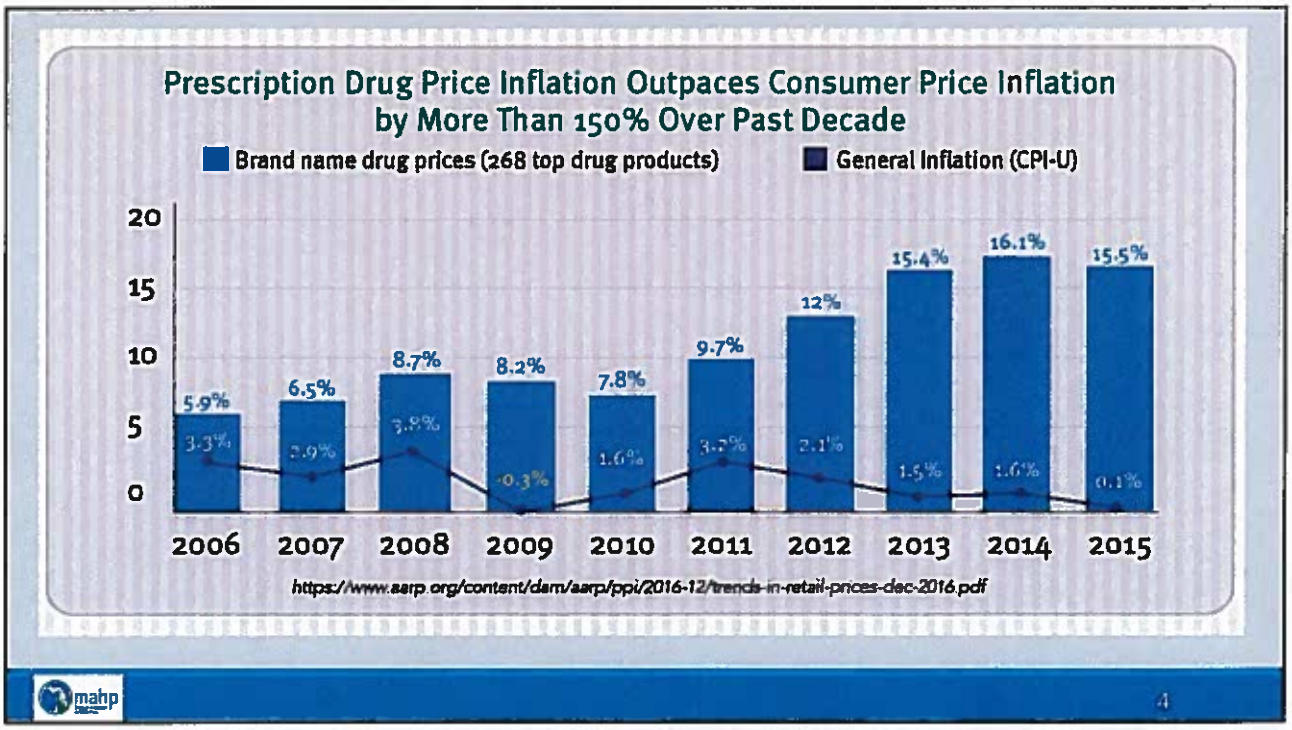
State Oral Chemo Therapy Parity Legislation will NOT impact persons with the following health coverage:

- Medicare (Part D or Advantage plans)
- Medicaid
- Employer sponsored and self-insured health plans that offer benefits to employees and retirees, such as unions
- Federal employees health benefits programs
- VA or Tricare benefits
- State sponsored health coverage (state of Michigan employees/retirees, local municipality provided coverage, teachers, firefighters etc.)



Dangerous Doubling

Average monthly oncology drug costs more than doubled:

$7,103 in 2006

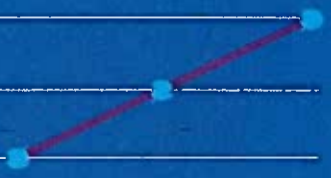
$15,535 in 2015

U.S. Cancer drug spending doubled over the past 5 years and is expected to double again by 2022.

2022: $100 billion

2017: $50 billion

2012: $24.8 billion



$79,000 In 2013

$150,000 In 2017

Average launch price for cancer drugs doubled and is expected to continue rising.

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Six Figure Tags. The New Normal.

All oncology drugs launched in 2017 carried prices more than $100,000 per year. This is what the new normal looks like:

[All costs annual]

Source: NIH Source: Reuters Source: The Balance

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High Cost Oncology Drugs Don't Always Correlate to Improved Health Outcomes

Drug	Total drug acquisition costs per patient and estimated increase in survival
Cetuximab	• US$ 80 352 • 1.2 months (non-small cell lung carcinoma)
Bevacizumab	• US$ 90 816 • 1.5 months (metastatic breast cancer – not statistically significant)
Erlotinib	• US$ 15 752 • 10 days (pancreatic cancer)
Sorafenib	• US$ 34 373 • 2.7 months (renal cell carcinoma)

WHO 2015 Report http://apps.who.int/medicinedocs/documents/s21793en/s21793en.pdf

$8,694
Median monthly cost in the US of eight cancer drugs

$2,587
Median monthly cost in the UK of the same eight cancer drugs

$2,741
Median monthly cost in Australia of the same eight cancer drugs

Source: Goldstein, D, Et al. J. Clinical Oncology 2016; Suppl; abstr. LBA 6500

Average Price of Six Cancer Drugs in Four Countries

Average price in US per unit	Dasatinib	Docetaxel	Erlotinib	Imatinib	Letrozole	Trastuzumab
	Per tablet	Per injection	Per tablet	Per tablet	Per tablet	Per injection
Generic:						
India		114.41	11.76	2.65	0.40	941.58
South Africa		241.41		12.46	2.76	
United Kingdom	79.06	496.18			0.40	
United States	162.39	305.73			0.18	
Brand:						
India		133.85				
South Africa	48.82	245.74	44.04	36.09	4.80	2,115.61
United Kingdom		602.26	57.40	43.81	4.97	631.25
United States		587.49	107.66	24.11	10.10	2,907.49

Source: IMS 2013.

Fortune 500 Health Care Companies by Industry

5 Slide Series, Volume 57
February, 2018

Category	Number of Companies	CY2016 Revenue (in $1,000,000s)	CY2016 Profits (in $1,000,000s)	CY2016 Profit Margin
Pharmaceuticals	10	$306,867	$67,748	22.1%
Medical Products and Equipment	7	$76,898	$10,375	13.5%
Health Care: Pharmacy and Other Services	5	$301,849	$10,214	3.4%
Health Care: Insurance and Managed Care	8	$499,645	$15,095	3.0%
Food and Drug Stores	2	$148,088	$4,339	2.9%
Health Care: Medical Facilities	8	$133,130	$1,953	1.5%
Wholesalers: Health Care	6	$487,733	$5,916	1.2%
Grand Total	46	$1,954,210	$115,638	5.9%

- The ten pharmaceutical companies represented the largest subcategory of health care companies in the 2017 *Fortune* 500. These companies had a collective profit margin of 22% and accounted for more than half of the total profits of *Fortune* 500 health care companies.

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Pharmaceuticals

5 Slide Series, Volume 57
February, 2018

Category/Company Name	Fortune's Rank	Rank by Profit	CY2016 Revenue (in $1,000,000s)	CY2016 Profits (in $1,000,000s)	CY2016 Profit Margin
Pharmaceuticals			$306,867	$67,748	22.1%
Johnson & Johnson	35	8	$71,890	$16,540	23.0%
Pfizer	54	32	$52,824	$7,215	13.7%
Merck	69	61	$39,807	$3,920	9.8%
Gilead Sciences	92	12	$30,390	$13,501	44.4%
AbbVie	111	40	$25,638	$5,953	23.2%
Amgen	123	29	$22,991	$7,722	33.6%
Eli Lilly	132	82	$21,222	$2,738	12.9%
Bristol-Myers Squibb	147	53	$19,427	$4,457	22.9%
Biogen	248	65	$11,449	$3,703	32.3%
Celgene	254	118	$11,229	$1,999	17.8%

- The 10 pharmaceutical companies in the *Fortune* 500 had the highest collective average profit margin across the health care industry during CY2016 (22.1%).
- Gilead Sciences earned the highest profit margin among these firms (44.4%), driven by their Hepatitis C drugs. The lowest profit margin among these ten companies during CY2016 (Merck at 9.8%) earned a larger profit margin than all *Fortune* 500 firms collectively earned.

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Unfortunately Solutions Addressing High Cost Oncology Drugs Needs to Be Done Federally

- Clarifying the definition of a drug under Medicare, regardless of route of administration
- Allow the U.S. to negotiate the pricing of drugs like done in other countries
- Allow for importation of drugs from Canada or other countries
- Utilizing the 340B Drug Pricing Program for oncology drugs
- Consider mandatory Patient Assistance Program for oncology drugs

Christine Shearer – Deputy Director, Office of Legislation & Advocacy
Karen A. Jonas, Pharmacist – MAHP Consultant

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Questions for lawmakers to ask constituents inquiring about Oral Chemo Therapy Parity Legislation

1) May I ask what type of Prescription Insurance Coverage You Currently Have (Medicare Part D or Medicare Advantage, Employer-sponsored Coverage, Medicaid, VA or Tricare, Small Group or Individual Market?)

   Reason why this is important: The current legislation will only impact insurance coverage changes for patients who have small group coverage.

   The Oral Chemo Therapy Parity Legislation will NOT impact persons covered under the following drug benefit plans:

   - Medicare (Part D or Advantage plans)
   - Medicaid
   - Employer sponsored or self-insured (ERISA) health plans that offer benefits to employees and retirees, such as unions (ex: GM, Ford or any group with more than 100 people)
   - Federal employees health benefits programs
   - VA or Tricare benefits
   - State sponsored health coverage (state of Michigan employees/retirees, local municipality provided coverage, teachers, firefighters etc.)

   Note: only 0.09% of Michigan's population has insurance coverage that would be impacted by this legislation.

2) Are you aware that insurance coverage for drugs (cancer drugs and other diseases) varies if the drug is an oral medication or is an injectable/infused medication due to Medicare regulation or federal requirements and is the reason why copays or co-insurance varies? This legislation will not change this coverage variance, have you been made aware of that?

   Note: Medicare covers injectable drugs (and some oral drugs) under the medical benefit, this was due to drug not covered under the Medicare program prior to 2006 and the creation of the Medicare Part D benefit. When Part D was implement, Congress unfortunately did not choose to move all drugs to coverage under the drug benefit and therefore a disparity exist today on what part of insurance covers drugs. Medical benefit for infused drugs and drug benefit for most oral drugs. This creates differing levels of cost-sharing coverage for drugs which does not change if this legislation is enacted. Congress needs to fix this issue.

3) How did the Michigan Cancer Society indicate to you that this legislation would help if the majority of insurance plans (Medicare, Medicaid, Employer sponsored) are not impacted, if drug coverage (medical verses drug coverage) cannot be impacted or changed at a state level and the legislation does not impact the high costs of drugs?

4) Are you aware that this legislation does not address the underlying issue of the high cost of cancer drugs?

   The premise for the legislation is to address cancer drug costs but this will not lower drug pricing.

   Prices of cancer drugs continue to grow far ahead of the costs of inflation. The mean new cancer drug price in 2017 was $200,000 compared to $40,000 the previous year. A one dose treatment of the newest infused cancer drug is $475.000.

   Prices for cancer drugs in the US are considerably higher than other countries (twice as much as Canada) because the US does not negotiate drug prices.